MARKED-UP AMENDMENTS TO THE SPECIFICATION

[0041] The compositions and methods of the present invention may comprise or use calcium in either chelated or non-chelated form. Chelation of calcium may affect its bioavailability. ~~CHELATED MINERALS, *available at* http://www.paws4us.com/minerals.html (last visited 08 November 2002).~~ This mineral is required for proper functioning of numerous intracellular and extracellular processes including, for example, muscle contraction, nerve conduction, blood coagulation, and of particular interest in the context of pregnancy and lactation, hormone release. In addition, the calcium ion plays a unique role in intracellular signaling and is involved in the regulation of many enzymes. THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 139 (Mark H. Beers, M.D. & Robert Berkow, M.D. eds., 17th ed. 1999). Calcium is available in forms known to those of skill in the art, including the form of calcium carbonate, the active ingredient in TUMS® (GlaxoSmithKline, Research Triangle Park, NC). The novel compositions and methods of the present invention may comprise or use calcium, specifically in amounts ranging from about 90 mg to about 110 mg and, in a specific embodiment, around 100 mg. Further, the novel compositions and methods of the present invention may comprise or use calcium in amounts less than about 160 mg. In addition, the novel compositions and methods of the present invention may comprise or use calcium in amounts ranging from about 0.001 mg to about 160 mg. In addition, the novel compositions and methods of the present invention may comprise or use calcium in amounts of 0 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg, 20 mg, 21 mg, 22 mg, 23 mg, 24 mg, 25 mg, 26 mg, 27 mg, 28 mg, 29 mg, 30 mg, 31 mg, 32 mg, 33 mg, 34 mg, 35 mg, 36 mg, 37 mg, 38 mg, 39 mg, 40 mg, 41 mg, 42 mg, 43 mg, 44 mg, 45 mg, 46 mg, 47 mg, 48 mg, 49 mg, 50 mg, 51 mg, 52 mg, 53 mg, 54 mg, 55 mg, 56 mg, 57 mg, 58 mg, 59 mg, 60 mg, 61 mg, 62 mg, 63 mg, 64 mg, 65 mg, 66 mg, 67 mg, 68 mg, 69 mg, 70 mg, 71 mg, 72 mg, 73 mg, 74 mg, 75 mg, 76 mg, 77 mg, 78 mg, 79 mg, 80 mg, 81 mg, 82 mg, 83 mg, 84 mg, 85 mg, 86 mg, 87 mg, 88 mg, 89 mg, 90 mg, 91 mg, 92 mg, 93 mg, 94 mg, 95 mg, 96 mg, 97 mg, 98 mg, 99 mg, 100 mg, 101 mg, 102 mg, 103 mg, 104 mg, 105 mg, 106 mg, 107 mg, 108 mg, 109 mg, 110 mg, 111 mg, 112 mg, 113 mg, 114 mg, 115 mg, 116 mg, 117 mg, 118 mg, 119 mg, 120 mg, 121 mg, 122 mg, 123 mg, 124 mg, 125 mg, 126 mg, 127 mg, 128 mg, 129 mg, 130 mg, 131 mg, 132 mg, 133 mg, 134 mg, 135 mg, 136 mg, 137 mg,

138 mg, 139 mg, 140 mg, 141 mg, 142 mg, 143 mg, 144 mg, 145 mg, 146 mg, 147 mg, 148 mg, 149 mg, 150 mg, 151 mg, 152 mg, 153 mg, 154 mg, 155 mg, 156 mg, 157 mg, 158 mg, 159 mg, or 160 mg.

[0042] The compositions and methods of the present invention may comprise or use iron in either chelated or non-chelated form. Chelation of iron may affect its bioavailability. ~~CHELATED MINERALS, *available at* http://www.paws4us.com/minerals.html (last visited 08 November 2002).~~ A primary function of iron is to carry oxygen to bodily tissues via the hemoglobin part of red blood cells. Supplemental intake of iron is critical to preventing anemia, a disorder associated with a variety of physiological states including, for example, pregnancy. Bothwell, 72(Supp.) AM. J. CLIN. NUTR. 257S-64S (2000). Severe anemia may have adverse effects upon a mother and a fetus. Specifically, significant depression of hemoglobin has been associated with poor pregnancy outcome. Black, 85(Supp. 2) BRIT. J. NUTR. S193-97 (2001); Sifakis & Pharmakides, 900 ANN. N.Y. ACAD. SCI. 125-36 (2000). One form of iron known in the art is ferrous fumarate (Jost Chemical, St. Louis, MO). The novel compositions and methods of the present invention may comprise or use iron, specifically in amounts ranging from about 58.5 mg to about 71.5 mg and, in a specific embodiment, around 65 mg. In addition, the novel compositions and methods of the present invention may comprise or use iron in amounts more than about 20 mg. In addition, the novel compositions and methods of the present invention may comprise or use iron in amounts of 0 mg, 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg, 20 mg, 21 mg, 22 mg, 23 mg, 24 mg, 25 mg, 26 mg, 27 mg, 28 mg, 29 mg, 30 mg, 31 mg, 32 mg, 33 mg, 34 mg, 35 mg, 36 mg, 37 mg, 38 mg, 39 mg, 40 mg, 41 mg, 42 mg, 43 mg, 44 mg, 45 mg, 46 mg, 47 mg, 48 mg, 49 mg, 50 mg, 51 mg, 52 mg, 53 mg, 54 mg, 55 mg, 56 mg, 57 mg, 58 mg, 59 mg, 60 mg, 61 mg, 62 mg, 63 mg, 64 mg, 65 mg, 66 mg, 67 mg, 68 mg, 69 mg, 70 mg, 71 mg, 72 mg, 73 mg, 74 mg, 75 mg, 76 mg, 77 mg, 78 mg, 79 mg, or 80 mg.

[0043] The compositions and methods of the present invention may comprise or use magnesium in either chelated or non-chelated form. Chelation of magnesium may affect its bioavailability. ~~CHELATED MINERALS, *available at* http://www.paws4us.com/minerals.html (last visited 08 November 2002).~~ Magnesium is important for over 300 different enzyme reactions. A primary function of magnesium is to bind to phosphate groups in adenosine triphosphate (ATP), thereby forming a complex that assists in the transfer of ATP phosphate. Magnesium also functions within cells as an allosteric activator of enzyme activity and for membrane stabilization. Magnesium also plays roles in nucleic acid synthesis, transcription

of DNA and RNA, amino acid activation, and protein synthesis. JAMES L.L. GROFF ET AL., ADVANCED NUTRITION AND HUMAN METABOLISM 341 (2d ed. 1996).

[0046] The compositions and methods of the present invention may comprise or use zinc in either chelated or non-chelated form. Chelation of zinc may affect its bioavailability. ~~CHELATED MINERALS, *available at* http://www.paws4us.com/minerals.html (last visited 08 November 2002).~~ Zinc plays a role in numerous metabolic activities such as nucleic acid production, protein synthesis, and development of the immune system. There are more than 200 zinc metalloenzymes including aldolase, alcohol dehydrogenase, RNA polymerase, and protein kinase C. Zima et al., 17 BLOOD PURIF. 182-86 (1999). Zinc stabilizes RNA and DNA structures, forms zinc fingers in nuclear receptors, and is a component of chromatin proteins involved in transcription and replication. Deficiencies of zinc during pregnancy have been shown to contribute to severe fetal abnormalities. Srinivas et al., 68(6) INDIAN J. PEDIATR. 519-22 (2001); Yang et al., 13(4) BIOMED. ENVIRON. SCI. 280-86 (2000); King, 71(Supp.) AM. J. CLIN. NUTR. 1334S-43S (2000). Zinc is available in many forms, such as zinc oxide (Reade Advanced Materials, Providence, RI) and zinc sulfate (United States Biological, Swampscott, MA). The novel compositions and methods of the present invention may comprise or use zinc, specifically in amounts ranging from about 22.5 mg to about 27.5 mg and, in a specific embodiment, around 25 mg.

[0047] The compositions and methods of the present invention may comprise or use copper in either chelated or non-chelated form. Chelation of copper may affect its bioavailability. ~~CHELATED MINERALS, *available at* http://www.paws4us.com/minerals.html (last visited 08 November 2002).~~ Copper is an important component of the process of gene expression. Deficiencies of copper may lead to anemia, neutropenia, and bone abnormalities in pregnant and lactating women. In addition, a fetus must accumulate copper at a rate of 50 $\mu g \times kg^{-1} \times d^{-1}$ over the latter half of pregnancy; any deficiency in accumulation may lead to low birth weight and protein-energy malnutrition. Uauy et al., 67(Supp.) AMER. J. CLIN. NUTR. 952S-59S (1998). Many forms of copper are known to those skilled in the art, including copper oxide (Reade Advanced Materials, Providence, RI). The novel compositions and methods of the present invention may comprise or use copper, specifically in amounts ranging from about 1.8 mg to about 2.2 mg and, in a specific embodiment, around 2.0 mg. The novel compositions and methods of the present invention may comprise or use copper, specifically in amounts of 0 mg, 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7

mg, 0.8 mg, 0.9 mg, 1.0 mg, 1.1 mg, 1.2 mg, 1.3 mg, 1.4 mg, 1.5 mg, 1.6 mg, 1.7 mg, 1.8 mg, 1.9 mg, 2.0 mg, 2.1 mg, 2.2 mg, 2.3 mg, 2.4 mg, 2.5 mg, 2.6 mg, 2.7 mg, 2.8 mg, 2.9 mg, or 3.0 mg.

REMARKS

Claims 187-201 and 217-231 are pending.

Preliminarily, the Examiner has indicated that the Information Disclosure Statement filed 22 March 2004 fails to comply with 37 C.F.R. §1.98(a)(2). Specifically, the Information Disclosure Statement fails to comply because it lists four English abstracts of foreign patents or patent publications under the category of foreign patent documents. The Examiner indicates that these abstracts should be listed under the category of other prior art or a copy of each foreign patent or patent publication should be submitted. Accordingly, Applicants are submitting herewith a Supplemental Information Disclosure Statement with these four foreign patents and patent publications listed and copies of each of the foreign patents and patent publications in their entirety. Additionally, Applicants are submitting herewith abstracts in English of the two Japanese patents and a concise statement of the relevance of each of these patents to the present application. Applicants respectfully request that the Examiner consider the foreign patents submitted with the Supplemental Information Disclosure Statement.

Additionally, the Specification has been objected to because it contains an embedded hyperlink and/or other form of brower-executable code. Specifically, paragraphs 0041-0043, 0046 and 0047 are objected to. Applicants have amended paragraphs 0041-0043, 0046 and 0047 of the Specification to remove the reference to the hyperlink.

I. REJECTIONS UNDER 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a)

The Examiner has rejected claims 187-201 under 35 U.S.C. §102(e) as anticipated by Nidamarty *et al.* (US 2003/0206969). Office Action of 11 August 2004 at page 3. The Examiner has further rejected claims 187-201 and 217-231 under 35 U.S.C. § 103(a) as being unpatentable over Nidamarty *et al.* (US 2003/0206969). Applicants respectfully traverse.

Without addressing the propriety of the Examiner's rejections, and specifically the Examiner's interpretation of what the cited reference teaches or suggests, Applicants respectfully submit that the present rejections should be withdrawn because the Nidamarty patent application publication is not prior art to the Applicants' invention. The Nidamarty patent application publication was based on an application provisionally filed on 2 May 2002 and published on 6 November 2003. The Declaration Of John A. Giordano Under 37 C.F.R. §1.131 ("the Giordano Declaration") and its associated evidence establish that the claimed

invention was reduced to practice before 2 May 2002, the provisional filing date of the Nidamarty patent application.

Referring to the Giordano Declaration, Mr. Giordano attests that he is a co-inventor of the above-identified patent application. Giordano Declaration at ¶ 1. Mr. Giordano has read and is familiar with the Office Action mailed 11 August 2004 pertaining to this application. *Id.* at ¶ 2. Mr. Giordano understands that in the Office Action mailed 11 August 2004 the Examiner rejected claims 187-201 as anticipated under 35 U.S.C. §102(e) over Nidamarty *et al.*, U.S. Patent Application Publication No. 2003/0206969 ("Nidamarty"), and claims 187-201 and 217-231 as being obvious under 35 U.S.C. §103(a) in view of Nidamarty. *Id.* at ¶ 3. Mr. Giordano has read and is familiar with Nidamarty. *Id.* at ¶ 4. It is Mr. Giordano's understanding that the Nidamarty patent application publication was filed provisionally on 2 May 2002 and published on 6 November 2003. *Id.* at ¶ 4.

Mr. Giordano has provided a copy of a company proprietary confidential monograph prepared and published internally (publication date redacted), under his supervision, before 2 May 2002. *Id.* at ¶ 5. The monograph summarizes and evidences the reduction to practice of the inventions disclosed and claimed in the present application Serial No. 10/790,027. *Id.* at ¶ 5. The monograph describes, *inter alia*, a formulation for Vitafol-OB caplets comprising Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc and copper, free of any other added minerals and any other added vitamins. *Id.* at ¶ 5. In addition, the conception and reduction to practice of the inventions disclosed and claimed in the present application and described in this monograph occurred in the United States. *Id.* at ¶ 5.

Therefore, in view of the Giordano Declaration, Applicants submit that the Nidamarty patent application publication is not §102(e) prior art to the Applicants' invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections.

II. REJECTION UNDER NONSTATUTORY DOUBLE PATENTING

The Examiner has provisionally rejected claims 187 and 217 under the doctrine of obviousness-type double patenting as being unpatentable over claims 45, 46, 287 and 288 of copending Application No. 10/315,159. Office Action of 11 August 2004 at page 5. Additionally, claims 187-201 and 217-231 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 45, 46, 287 and 288 of

copending Application No. 10/315,159 in view of Manning et al. (U.S. Patent 6,569,445) or Nidamarty et al. (US 2003/0206969). *Id.* at page 6. U.S. Application No. 10/315,159 issued as U.S. Patent No. 6,814,983 on 9 November 2004.

The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting ground. Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully and properly defer addressing the present rejection until there is allowable subject matter in the present application. Only then is it proper to assess the propriety of the Examiner's rejection in view of the allowed claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections until claims are allowed in the present application.

CONCLUSION

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

11 February 2005

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